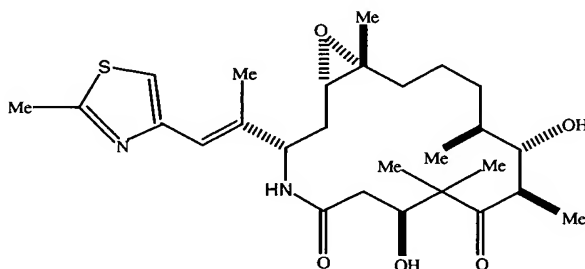


We claim:

1. A method for treating cancer or other proliferative diseases in a mammal, comprising:

a) preparing a pharmaceutical composition comprising an active ingredient and one or more pharmaceutically acceptable carriers, excipients or diluents thereof; wherein the active ingredient comprises an effective amount of a crystalline material of an epothilone analog represented by formula I:



I

wherein the crystalline material is Form A and optionally Form B;

and

b) administering the pharmaceutical composition to the mammal;

wherein the Form A is characterized by:

i) unit cell parameters approximately equal to the following:

Cell dimensions $a = 14.152(6) \text{ \AA}$
 $b = 30.72(2) \text{ \AA}$
 $c = 6.212(3) \text{ \AA}$
 Volume = $2701(4) \text{ \AA}^3$

Space group $P2_12_12_1$
 Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.247

Melting point 182-185°C (decomposition); and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta

($\text{CuK}\alpha \lambda = 1.5406 \text{ \AA}$ at 22°C): 5.69, 6.76, 8.38, 11.43, 12.74, 13.62, 14.35, 15.09,

15.66, 16.43, 17.16, 17.66, 18.31, 19.03, 19.54, 20.57, 21.06, 21.29, 22.31, 23.02,

23.66, 24.18, 14.98, 25.50, 26.23, 26.23, 26.46, 27.59, 28.89, 29.58, 30.32, 31.08 and

31.52; and/or

- ii) a powder x-ray diffraction substantially as shown in FIG. 1 and a Raman spectrum substantially as shown in FIG. 5; and/or
- iii) a solubility in water of 0.1254, a solubility in a 3% aqueous solution of polysorbate 80 of 0.2511, a melting point with decomposition between 182-185°C and a heat of solution of 20.6 kJ/mol;

and

wherein the Form B, if present, is characterized by:

- i) unit cell parameters approximately equal to the following:

Cell dimensions $a = 16.675(2) \text{ \AA}$
 $b = 28.083(4) \text{ \AA}$
 $c = 6.054(1) \text{ \AA}$
 Volume = $2835(1) \text{ \AA}^3$

Space group $P2_12_12_1$
 Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.187

Melting point 191-199°C decomposition; and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta ($\text{CuK}\alpha \lambda = 1.5406 \text{ \AA}$ at 22°C): 6.17, 10.72, 12.33, 14.17, 14.93, 15.88, 16.17, 17.11, 17.98, 19.01, 19.61, 20.38, 21.55, 21.73, 22.48, 23.34, 23.93, 24.78, 25.15, 25.90, 26.63, 27.59, 28.66, 29.55, 30.49 and 31.22; and/or

- ii) a powder x-ray diffraction substantially as shown in FIG. 2 and a Raman spectrum substantially as shown in FIG. 6; and/or

- iii) a solubility in water of 0.1907, a solubility in a 3% aqueous solution of polysorbate 80 of 0.5799, a melting point with decomposition between 191-199 °C and a heat of solution of 9.86 kJ/mol.

2. The method according to claim 1 wherein the Form A is characterized by:

unit cell parameters approximately equal to the following:

Cell dimensions $a = 14.152(6) \text{ \AA}$
 $b = 30.72(2) \text{ \AA}$
 $c = 6.212(3) \text{ \AA}$

- Volume = 2701(4) Å³
- Space group P2₁2₁2₁
Orthorhombic
- Molecules/unit cell 4
- 5 Density (calculated) (g/cm³) 1.247
- Melting point 182-185°C (decomposition); and
characteristic peaks in the powder x-ray diffraction pattern at values of two theta (CuKα
λ=1.5406 Å at 22°C): 5.69, 6.76, 8.38, 11.43, 12.74, 13.62, 14.35, 15.09, 15.66, 16.43, 17.16,
17.66, 18.31, 19.03, 19.54, 20.57, 21.06, 21.29, 22.31, 23.02, 23.66, 24.18, 14.98, 25.50,
10 26.23, 26.23, 26.46, 27.59, 28.89, 29.58, 30.32, 31.08 and 31.52.
3. The method according to claim 1 wherein the Form A is characterized by: a powder x-ray
diffraction substantially as shown in FIG. 1 and a Raman spectrum substantially as shown in
FIG. 5.
- 15 4. The method according to claim 1 wherein the Form A is characterized by: a solubility in
water of 0.1254, a solubility in a 3% aqueous solution of polysorbate 80 of 0.2511, a melting
point with decomposition between 182-185°C and a heat of solution of 20.6 kJ/mol.
- 20 5. The method according to claim 1 wherein the mammal is a human.
6. The method according to claim 5 wherein the effective amount is in the range of from
about 0.05 to about 200 mg/kg/day.
- 25 7. The method according to claim 1 wherein the cancer is breast cancer or lung cancer.
8. The method according to claim 1 wherein the pharmaceutical composition is administered
parenterally.
- 30 9. The method according to claim 1 wherein the pharmaceutical composition comprises the
Form A and the Form B.

10. The method according to claim 9 wherein the mammal is a human and the effective amount is in the range of from about 0.05 to about 200 mg/kg/day.

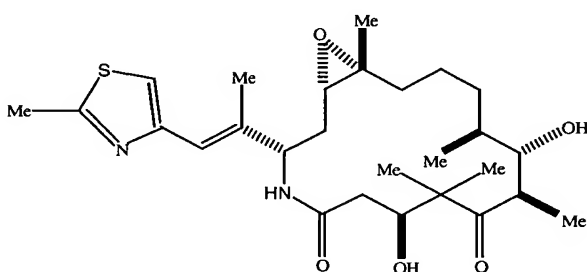
11. The method according to claim 9 wherein the cancer is breast cancer or lung cancer.

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12. A method for treating cancer or other proliferative diseases in a mammal, comprising:

a) preparing a pharmaceutical composition comprising an active ingredient and one or more pharmaceutically acceptable carriers, excipients or diluents thereof; wherein the active ingredient comprises an effective amount of a crystalline material of an epothilone analog

10 represented by formula I:



I

wherein the crystalline material is Form B and optionally Form A; and

b) administering the pharmaceutical composition to the mammal;

15 wherein the Form A, if present, is characterized by:

i) unit cell parameters approximately equal to the following:

Cell dimensions $a = 14.152(6) \text{ \AA}$

$b = 30.72(2) \text{ \AA}$

$c = 6.212(3) \text{ \AA}$

20 Volume = $2701(4) \text{ \AA}^3$

Space group $P2_12_12_1$

Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.247

25 Melting point $182\text{--}185^\circ\text{C}$ (decomposition); and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta

($\text{CuK}\alpha \lambda = 1.5406 \text{ \AA}$ at 22°C): 5.69, 6.76, 8.38, 11.43, 12.74, 13.62, 14.35, 15.09,

15.66, 16.43, 17.16, 17.66, 18.31, 19.03, 19.54, 20.57, 21.06, 21.29, 22.31, 23.02,

23.66, 24.18, 14.98, 25.50, 26.23, 26.23, 26.46, 27.59, 28.89, 29.58, 30.32, 31.08 and 31.52; and/or

ii) a powder x-ray diffraction substantially as shown in FIG. 1 and a Raman spectrum substantially as shown in FIG. 5; and/or

5 iii) a solubility in water of 0.1254, a solubility in a 3% aqueous solution of polysorbate 80 of 0.2511, a melting point with decomposition between 182-185°C and a heat of solution of 20.6 kJ/mol;

and

wherein the Form B is characterized by:

10 i) unit cell parameters approximately equal to the following:

Cell dimensions	a = 16.675 (2) Å
	b = 28.083(4) Å
	c = 6.054(1) Å
	Volume = 2835(1) Å ³

15 Space group P2₁2₁2₁
Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm³) 1.187

Melting point 191-199°C decomposition; and

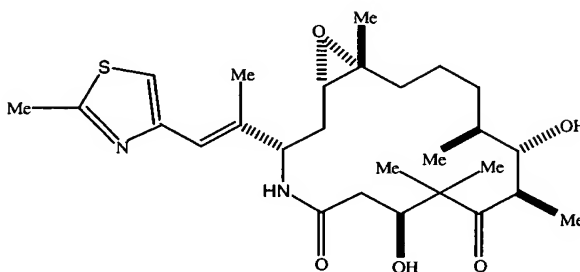
20 characteristic peaks in the powder x-ray diffraction pattern at values of two theta (CuKα λ=1.5406 Å at 22°C): 6.17, 10.72, 12.33, 14.17, 14.93, 15.88, 16.17, 17.11, 17.98, 19.01, 19.61, 20.38, 21.55, 21.73, 22.48, 23.34, 23.93, 24.78, 25.15, 25.90, 26.63, 27.59, 28.66, 29.55, 30.49 and 31.22; and/or

25 ii) a powder x-ray diffraction substantially as shown in FIG. 2 and a Raman spectrum substantially as shown in FIG. 6; and/or

iii) a solubility in water of 0.1907, a solubility in a 3% aqueous solution of polysorbate 80 of 0.5799, a melting point with decomposition between 191-199 °C and a heat of solution of 9.86 kJ/mol.

30 13. A process for preparing a pharmaceutical composition comprising: mixing an active ingredient with one or more pharmaceutically acceptable carriers, excipients or diluents thereof;

wherein the active ingredient comprises an effective amount of a crystalline material of an epothilone analog represented by formula I:



I

wherein the crystalline material is Form A and optionally Form B:

wherein the Form A is characterized by:

i) unit cell parameters approximately equal to the following:

Cell dimensions $a = 14.152(6) \text{ \AA}$

$b = 30.72(2) \text{ \AA}$

$c = 6.212(3) \text{ \AA}$

Volume = $2701(4) \text{ \AA}^3$

Space group $P2_12_12_1$

Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.247

Melting point $182\text{--}185^\circ\text{C}$ (decomposition); and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta

($\text{CuK}\alpha \lambda = 1.5406 \text{ \AA}$ at 22°C): 5.69, 6.76, 8.38, 11.43, 12.74, 13.62, 14.35, 15.09,

15.66, 16.43, 17.16, 17.66, 18.31, 19.03, 19.54, 20.57, 21.06, 21.29, 22.31, 23.02,

23.66, 24.18, 14.98, 25.50, 26.23, 26.23, 26.46, 27.59, 28.89, 29.58, 30.32, 31.08 and 31.52;

ii) a powder x-ray diffraction substantially as shown in FIG. 1 and a Raman spectrum substantially as shown in FIG. 5; or

iii) a solubility in water of 0.1254, a solubility in a 3% aqueous solution of polysorbate 80 of 0.2511, a melting point with decomposition between $182\text{--}185^\circ\text{C}$ and a heat of solution of 20.6 kJ/mol ;

and

wherein Form B, if present, is characterized by:

i) unit cell parameters approximately equal to the following:

Cell dimensions $a = 16.675(2) \text{ \AA}$

$b = 28.083(4) \text{ \AA}$

$c = 6.054(1) \text{ \AA}$

Volume = $2835(1) \text{ \AA}^3$

Space group $P2_12_12_1$

Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.187

Melting point $191\text{-}199^\circ\text{C}$ decomposition; and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta ($\text{CuK}\alpha \lambda = 1.5406 \text{ \AA}$ at 22°C): 6.17, 10.72, 12.33, 14.17, 14.93, 15.88, 16.17, 17.11, 17.98, 19.01, 19.61, 20.38, 21.55, 21.73, 22.48, 23.34, 23.93, 24.78, 25.15, 25.90, 26.63, 27.59, 28.66, 29.55, 30.49 and 31.22 ;

ii) a powder x-ray diffraction substantially as shown in FIG. 2 and a Raman spectrum substantially as shown in FIG. 6; or

iii) a solubility in water of 0.1907, a solubility in a 3% aqueous solution of polysorbate 80 of 0.5799, a melting point with decomposition between $191\text{-}199^\circ\text{C}$ and a heat of solution of 9.86 kJ/mol .

14. The process according to claim 13 wherein the Form A is characterized by:

unit cell parameters approximately equal to the following:

Cell dimensions $a = 14.152(6) \text{ \AA}$

$b = 30.72(2) \text{ \AA}$

$c = 6.212(3) \text{ \AA}$

Volume = $2701(4) \text{ \AA}^3$

Space group $P2_12_12_1$

Orthorhombic

Molecules/unit cell 4

Density (calculated) (g/cm^3) 1.247

Melting point $182\text{-}185^\circ\text{C}$ (decomposition); and

characteristic peaks in the powder x-ray diffraction pattern at values of two theta ($\text{CuK}\alpha$ $\lambda=1.5406 \text{ \AA}$ at 22°C): 5.69, 6.76, 8.38, 11.43, 12.74, 13.62, 14.35, 15.09, 15.66, 16.43, 17.16, 17.66, 18.31, 19.03, 19.54, 20.57, 21.06, 21.29, 22.31, 23.02, 23.66, 24.18, 14.98, 25.50, 26.23, 26.23, 26.46, 27.59, 28.89, 29.58, 30.32, 31.08 and 31.52.

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15. The process according to claim 13 wherein the Form A is characterized by: a powder x-ray diffraction substantially as shown in FIG. 1 and a Raman spectrum substantially as shown in FIG. 5.

10 16. The process according to claim 13 wherein the Form A is characterized by: a solubility in water of 0.1254, a solubility in a 3% aqueous solution of polysorbate 80 of 0.2511, a melting point with decomposition between $182\text{--}185^\circ\text{C}$ and a heat of solution of 20.6 kJ/mol .

15 17. The process according to claim 13 wherein the pharmaceutical composition comprises the Form A and the Form B.

18. The process according to claim 17 wherein the Form B is characterized by:
unit cell parameters approximately equal to the following:

Cell dimensions	a = $16.675(2) \text{ \AA}$
20	b = $28.083(4) \text{ \AA}$
	c = $6.054(1) \text{ \AA}$
	Volume = $2835(1) \text{ \AA}^3$
Space group	$P2_12_12_1$
	Orthorhombic
25 Molecules/unit cell	4
Density (calculated) (g/cm^3)	1.187
Melting point	$191\text{--}199^\circ\text{C}$ decomposition; and
	characteristic peaks in the powder x-ray diffraction pattern at values of two theta ($\text{CuK}\alpha$ $\lambda=1.5406 \text{ \AA}$ at 22°C): 6.17, 10.72, 12.33, 14.17, 14.93, 15.88, 16.17, 17.11, 17.98, 19.01,
30	19.61, 20.38, 21.55, 21.73, 22.48, 23.34, 23.93, 24.78, 25.15, 25.90, 26.63, 27.59, 28.66,
	29.55, 30.49 and 31.22.

19. The process according to claim 17 wherein the Form B is characterized by: a powder x-ray diffraction substantially as shown in FIG. 2 and a Raman spectrum substantially as shown in FIG. 6.
- 5 20. The process according to claim 17 wherein the Form B is characterized by: a solubility in water of 0.1907, a solubility in a 3% aqueous solution of polysorbate 80 of 0.5799, a melting point with decomposition between 191-199 °C and a heat of solution of 9.86 kJ/mol.